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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

CLAIRE C. HAGGARTY, individually and on
behalf of all others similarly situated,

Plaintiff,

vs.

**STRYKER ORTHOPAEDICS (aka STRYKER
ORTHOPEDICS; aka STRYKER
ORTHOPEDICS, INC.); HOWMEDICA
OSTEONICS CORPORATION; STRYKER
CORPORATION; and STRYKER SALES
CORPORATION,**

Defendants.

Case No.

CLASS ACTION COMPLAINT

COMPLAINT FOR:

**(1) VIOLATION OF THE
CARTWRIGHT ACT (CAL.
BUS. & PROF. CODE
§§ 16700 *et seq.*);**

**(2) VIOLATION OF THE
CALIFORNIA UNFAIR
COMPETITION LAW (CAL.
BUS. & PROF. CODE
§§ 17200 *et seq.*)**

JURY TRIAL DEMANDED

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Pursuant to the Federal Rules of Civil Procedure, Plaintiff, on behalf of herself and all other similarly situated persons who are or at the relevant times were California residents, hereby bring this action for compensatory damages, treble damages, and equitable relief, including restitution and/or injunctive relief, under California's antitrust statutes, the Cartwright Act (Cal. Bus. & Prof. Code §§ 16700 *et seq.*), and California's unfair competition law (Cal. Bus. & Prof. Code §§ 17200 *et seq.*). Plaintiff complains and alleges on information and belief except as to those paragraphs applicable to the named Plaintiff, which are based on personal knowledge, as follows:

I. NATURE OF THE ACTION

1. This action arises out of a pervasive kickback scheme orchestrated by one of the largest manufacturers of artificial hip and knee replacement devices, which uses phony consulting agreements with orthopedic surgeons to cleverly mask disguised kickbacks paid to doctors and/or hospitals in return for choosing which manufacturer's device to use during a patient's surgery. Rather than promote safety and effectiveness, the choice of medical device is thereby governed by the financial gain for doctors or hospitals, and the prospect of increased market share for the Defendant Stryker companies and their co-conspirators.

2. While the kickback scheme dates back at least to 2002, Stryker reportedly began cooperating with federal investigators in October 2005, which apparently enabled federal officials to develop incriminating information on similar misconduct by the other big four manufacturers of hip and knee implants. As a result, the U.S. Department of Justice has entered into a Non Prosecution Agreement with Stryker Orthopedics, a division of Howmedica Osteonics Corporation (which in turn is a subsidiary of Stryker Corporation). A copy of the Stryker Non Prosecution Agreement is attached hereto as Exhibit A.

II. JURISDICTION, VENUE, INTRADISTRICT ASSIGNMENT

3. **Subject matter jurisdiction:** This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1332(a)(1), because Plaintiff is a resident of California

1 (and members of the putative class all are or at the relevant times were residents of
2 California) whereas Defendants are all incorporated and have their principal places of
3 business in other states, and the amount in controversy exceeds the jurisdictional
4 minimum of this Court.

5 4. **Personal jurisdiction:** This court has personal jurisdiction over each of the
6 Defendants because each was engaged in unlawful acts that were directed at and/or
7 caused injury to persons residing in or located in the Northern District of California as
8 well as throughout California and the other United States.

9 5. **Venue:** Venue is proper in this judicial district pursuant to 28 U.S.C.
10 § 1391(a)(2), because a substantial part of the events giving rise to Plaintiff's claims
11 occurred in this district.

12 6. **Intradistrict assignment:** Assignment to the San Francisco or Oakland
13 Division is appropriate pursuant to Civil L.R. 3-2(c) because a substantial part of the
14 events giving rise to the claims in this action occurred in San Mateo County.

15 **III. THE PARTIES**

16 **A. Plaintiff**

17 7. Plaintiff Claire C. Haggarty ("Plaintiff") is, and at all times relevant to this
18 action was, a resident of San Mateo County.

19 **B. Defendants**

20 8. On information and belief, Defendant **Stryker Orthopaedics**,
21 headquartered in New Jersey, is a division of Defendant **Howmedica Osteonics**
22 **Corporation**, headquartered in and incorporated under the laws of New Jersey, which is
23 a subsidiary of Defendant Stryker Corporation. On information and belief, Defendant
24 Stryker Orthopedics has sometimes been known as **Stryker Orthopedics** and/or **Stryker**
25 **Orthopedics, Inc.**

26 9. Defendant **Stryker Corporation** is headquartered in and incorporated
27 under the laws of Michigan.

10. Defendant **Stryker Sales Corporation**, a subsidiary of Defendant Stryker Corporation, is headquartered in and incorporated under the laws of Michigan.

11. The defendants identified in the preceding paragraphs are referred to collectively herein as “**Stryker**” or “**Defendants.**”

C. Unnamed Co-Conspirators

12. At all relevant times, other individuals and/or other entities willingly conspired with Defendants in their unlawful restraint of trade, kickback scheme, and/or other unlawful conduct. All averments herein against named Defendants are also averred against these unnamed co-conspirators as though set forth at length.

D. Agents

13. At all relevant times, Defendants, and each of them, in performing the acts alleged in this complaint, were acting as the agents, employees, and/or representatives of each other, and were acting within the full course and scope of their agency and employment with the full knowledge, consent, permission, authorization, and ratification, either express or implied, of each of the other Defendant.

14. Each of the Defendants has participated as members of the conspiracy, and has acted with or in furtherance of said conspiracy, or aided or assisted in carrying out the purposes of the conspiracy, and has performed acts and made statements in furtherance of the conspiracy and other violations of California law. Each of the Defendants acted both individually and in alignment with other Defendants, with full knowledge of their respectful wrongful conduct. As such, the Defendants conspired together, building on each other’s wrongdoing, to accomplish the acts outlined in this complaint. Defendants are sued individually as principals, participants, and aiders and abettors in the wrongful conduct complained of; the liability of each arises from the fact that each has engaged in all or part of the improper acts, plans, schemes, conspiracies, or transactions complained of herein.

IV. TRADE AND COMMERCE

15. Throughout the Class period, there was a continuous flow of commerce

1 between **Stryker** and its co-conspirators, into and out of California, in the hip and knee
 2 implant devices produced by **Stryker**, and in payments and other forms of consideration
 3 provided by **Stryker** to its co-conspirators. Defendants' unlawful activities, as described
 4 herein, took place within the flow of commerce into and out of California and among the
 5 other states, and had a direct, substantial, and reasonably foreseeable effect on interstate
 6 and international commerce in the United States.

7 **V. FACTUAL ALLEGATIONS**

8 **A. Stryker, "One of the World's Leading Medical Technology** 9 **Companies," and Just Four Other Companies Together** 10 **"Control" the Highly Lucrative Market in Hip and Knee** 11 **Implants**

12 16. The market for hip and knee implant products is huge, highly lucrative, and
 13 tightly concentrated. In the United States, the federal Department of Health and Human
 14 Services ("HHS") reports that more than 700,000 hip and knee replacement surgeries are
 15 performed every year. HHS's Assistant Inspector General for Legal Affairs, Gregory E.
 16 Demske, recently testified to the U.S. Senate Special Committee on Aging that sales of
 17 orthopedic devices for hips and knees exceeded \$5.1 billion in 2005 in the United States.
 (He also testified that global sales of the same products that year topped \$9.4 billion.)

18 17. In late September 2007, the U.S. Attorney for the District of New Jersey,
 19 Christopher J. Christie, reported that just five companies – **Stryker** Orthopedics, Inc.
 20 [sic], among them – control almost 95 percent of sales in the market for hip and knee
 21 surgical implants. On the basis of the HHS official's testimony that the other four
 22 companies "controlled almost 75 percent of the hip and knee replacement market," it may
 23 be inferred that **Stryker** alone accounts for roughly one fifth of the sales in this market.

24 18. With justification, then, **Stryker** Corporation's annual report to the
 25 Securities and Exchange Commission for the year ending December 31, 2007, introduced
 26 the **Stryker** corporate family as "one of the world's leading medical technology
 27 companies." On a worldwide basis for 2007, **Stryker** Corporation reported gross profits
 28 of \$4.135 billion on \$6 billion in net sales (up by 17 percent over the figure for 2006),

1 with orthopedic implants accounting for 60 percent of the global sales figure, or \$3.57
 2 billion. (These figures reflect more than the hip and knee products: **Stryker's** orthopedic
 3 implant line also includes shoulder, spinal, and craniomaxillofacial implant systems, bone
 4 cement, and a bone growth factor product.)

5 **B. A Federal Investigation Has Found That Stryker, Like the Other**
 6 **Four Companies, Maintained Its Overwhelming Market**
 7 **Dominance Through a "Pervasive" and Anti-competitive Scheme**
 8 **of Kickbacks to Hip and Knee Surgeons, in Violation of Federal**
 9 **and California Law**

10 19. **Stryker** also reported substantial "cost of sales," at more than 31 percent of
 11 sales in 2007, along with a component of R&D and engineering expenses that amounted
 12 to an additional 6.3% of sales. Whether either of these categories was accurately reported
 13 is questionable, however, in light of the announcement made by U.S. Attorney Christie on
 14 September 27, 2007.

15 20. In a five-page press release, "Five Companies in Hip and Knee
 16 Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and
 17 Monitoring," Mr. Christie announced that the U.S. Department of Justice had settled
 18 criminal complaints, and HHS had settled civil claims, against the other four big hip/knee
 19 implant companies arising out of a multi-agency federal investigation that had confirmed
 20 the existence of a massive pattern of "financial inducements paid to surgeons to use their
 21 products" in hip and knee implant surgeries, in violation of several federal anti-kickback
 22 and false claim statutes. Claims would be held in abeyance against **Stryker** only because
 23 it was the first of the big five hip/knee implant companies to cooperate with federal
 24 investigators. (See Exhibit A attached hereto, Non Prosecution Agreement.)

25 21. As Mr. Demske of HHS summarized the findings of the federal
 26 investigation to the Senate Special Committee on Aging, although some of the
 27 companies' payments to surgeons were legitimate,

28 in certain consulting arrangements the companies **derived little value
 beyond the acquisition of increased sales of artificial hip and knee
 implants** used by the consulting surgeons. The companies also failed to
 oversee and audit the work performed by the surgeons under the consulting
 agreements. For example, the surgeons engaged in "work" activities that

involved minimal or no actual work being performed, but created a billable event for the consultant, such as the following:

- Consulting agreements required the physicians to report periodically the services that they provided to the company to support the consulting fees. Some consulting agreements had only vague requirements for these reports. When the consulting agreements did include specific requirements, these reports often failed to include the required information or were drafted by sales representatives rather than by the consultants.
- In addition to reports documenting services provided, some companies paid consultants a fee, typically \$5,000, for each quarterly report that included information on market trends, activity in the operating room, and product issues. However, these work reports typically included only cursory descriptions and were often duplicated from quarter to quarter. Many of these quarterly reports were of little or no value to the companies.
- The companies sponsored consultant panel meetings at resort locations and reimbursed the physicians for travel expenses. These meetings would only be held for a few hours each day and physician consultants who presented at these meetings typically spoke for a minimal time period, sometimes for as few as 10 minutes. Although the remainder of the day was available for recreational activities paid for by the company, the consultants were compensated \$5,000 for a full day of work.
- Consultants billed for training sessions that involved sales representatives observing the surgeon while in the operating room. Some of these training sessions were held for experienced sales representatives who, as part of their jobs, had been servicing the surgeons in their sales regions for some time. These sales representatives were already required to be present in the operating room with the surgeons to assist them with the procedures. These training sessions lasted for 1 to 2 hours, but the consultants billed for an 8- to 10-hour workday.
- Some companies entered into product development agreements with consultant physicians, offering them royalty payments once the products were launched. These agreements provided for annual payments of hundreds of thousands or millions of dollars for up to 20 years. The design teams included up to 20 physicians, some of whom were added after the projects were more than halfway completed. The companies often did not measure the contributions of individual physicians and up to half the members of some teams appeared to have performed little or no work.

1 (Emphasis added.) Mr. Demske also advised the Senate panel that from 2002 through
2 2006, the four companies other than **Stryker** had “paid physician consultants over
3 \$800 million under the terms of roughly 6,500 consulting agreements.”

4 22. If they failed to receive the benefits that the contracts supposedly were
5 designed to produce, what was in it for **Stryker** and the other companies? Surgeon
6 loyalty, and pumped-up sales of their products. As the federal charges (now deferred,
7 pursuant to the settlement agreements) put it, each company’s “consulting agreements
8 with certain orthopedic surgeons [were] designed, in part, to induce the surgeons to use,
9 and cause the purchase of, [the company]’s hip and knee reconstruction and replacement
10 products.”

11 23. Several sources referred to in Mr. Demske’s testimony suggest that such
12 agreements were effective in producing the unlawful result that the participating company
13 desired. Referring to articles published in the *Journal of the American Medical*
14 *Association* and the *New England Journal of Medicine*, he testified that researchers “have
15 found that . . . financial industry-physician relationships are pervasive and that the
16 impulse to reciprocate for even small gifts has a powerful influence on behavior.” One of
17 the sources he cited, a 1994 study of full-time attending physicians in a university hospital
18 and their interactions with drug companies, found along several dimensions that
19 “[r]equests by physicians that drugs be added to a hospital formulary were strongly and
20 specifically associated with the physicians’ interactions with the companies
21 manufacturing the drugs.” As Mr. Demske indicated, there is no reason to confine the
22 implications of this study to the arena of physicians’ or surgeons’ interactions with
23 pharmaceutical companies.

24 24. Two measures reflect how “pervasive” the collusive practices have been
25 between the five companies, including **Stryker**, and certain surgeons, and how important
26 they have been to the companies’ dominance in the hip/knee implant market. First, U.S.
27 Attorney Christie announced in his September 27, 2007, press release that the price of
28 settling the criminal and civil federal claims that had been filed against the four

1 companies other than **Stryker** included \$311 million in company payments to the federal
 2 government. But second, the day after this news was made public, the share price in the
 3 four companies' stock reportedly rose – signaling investors' perception that the
 4 companies had gotten off lightly relative to the vast financial benefits that they continue
 5 to reap.

6 25. Besides the payments agreed to by the four companies other than **Stryker**,
 7 all five companies, including **Stryker**, agreed to “prominently feature” on their websites
 8 public disclosures of the amounts they pay to surgeons on a periodic basis. The
 9 disclosures now accessible (with some effort) on **Stryker**'s website confirm that **Stryker**
 10 has paid millions of dollars of direct and in-kind payments to orthopedic surgeons
 11 throughout the United States, including California, during 2007 alone – by which time
 12 **Stryker** was presumably making greater efforts to comply with legal requirements.

13 C. **Stryker's Unlawful Scheme to Restrain Competition in Hip and**
 14 **Knee Surgery Products Has Inflated the Price of Hip and Knee**
 15 **Implants, Resulting in Financial Injury Not Only to Publicly**
 16 **Funded Medical Care Programs But Also to Plaintiff and Other**
 17 **Private-Pay Patients**

18 26. The practices summarized above have sustained an oligopolistic market that
 19 Mr. Demske accurately characterized as “controlled” by just a handful of manufacturers,
 20 **Stryker** among them. This market structure inherently inflates the prices of the hip and
 21 knee implant products sold by the big five.

22 27. The actions taken by federal officials reflect well-founded concern that such
 23 inflated pricing creates a huge and illegal drain on publicly funded health care programs,
 24 like Medicare (which, as the federal officials reported, pays for approximately two-thirds
 25 of all hip and knee replacement surgeries in the U.S.) and Medicaid – in California, Medi-
 26 Cal. But private-pay patients are also harmed by **Stryker**'s practices.

27 28. Private-pay patients, including both uninsured persons and persons with
 28 private health insurance coverage where their co-pay is a percentage of the overall charge,
 are harmed financially by virtue of higher co-pays and/or other out-of-pocket expenses.
 In addition, over time an increment of the health insurance premiums has been

1 attributable to the general impact of **Stryker**'s improper, collusive, anti-competitive
2 practices in contributing to the overall rise in health care costs. The settlements reached
3 by federal prosecutors, and their Non Prosecution Agreement with **Stryker**, being
4 confined to federally funded health care programs, do nothing to remedy these financial
5 harms.

6 29. Thus, Plaintiff is compelled to bring this action, on behalf of herself and
7 other similarly situated Californians, in order to receive restitution of amounts that
8 **Stryker**'s unlawful practices have wrongfully caused them to pay during the Class
9 period.

10 30. Plaintiff Claire C. Haggarty underwent hip replacement surgery in January
11 2006. One or more **Stryker** products were implanted or otherwise used in her surgery.
12 Based on records that she has kept, Plaintiff Haggarty has paid approximately \$3,600 or
13 more in out-of-pocket expenses for the surgery.

14 **VI. CLASS ACTION ALLEGATIONS**

15 31. Plaintiff brings this action on her own behalf and as a class action pursuant
16 to rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of the
17 following class (the "Class"):

18 All individuals who are, or at the relevant time were, residents of California
19 who either were uninsured or had a private health care insurance policy
20 pursuant to which they paid a percentage of the total costs of surgical
procedures, and who had hip or knee implant surgery during the Class
period that involved the use of Stryker products.

21 32. Plaintiff does not know the exact number of Class members, but the number
22 of such individuals may be determined through Defendants' records, and their identities
23 may be derived from such records. Thus, the Class is ascertainable. Based on federal
24 investigators' estimate that approximately 700,000 knee or hip implant surgeries are
25 performed in the United States every year, and that roughly one third of such surgeries are
26 not covered by Medicare, and based on Census data indicating that approximately 12% of
27 the total U.S. population now lives in California, Plaintiff estimates roughly that upwards
28 of 25,000 private-pay patients have hip or knee implant surgery in California every year.

1 Assuming that Stryker products are implanted in roughly one fifth of these surgeries, the
2 Class would include roughly 5,000 patients implanted with Stryker hip or knee products
3 every year. Thus, the Class satisfies the numerosity criterion under rule 23(a).

4 33. There are questions of fact or law common to the Class, including without
5 limitation the following:

6 a. Whether the **Stryker** Defendants, or any of them, engaged in an
7 ongoing business practice during the Class period of providing payments or other
8 consideration of monetary value to hip and/or knee surgeons in accordance with
9 agreements reached between **Stryker** and such surgeons through which **Stryker** sought
10 to induce such surgeons to choose its products in hip or knee implant surgery;

11 b. Whether **Stryker** sought to conceal such payments or consideration
12 provided to hip and/or knee implant surgeons, or to disguise the actual basis of such
13 payments or other consideration provided to such surgeons, and, if so, over what time
14 period **Stryker** continued to engage in such practices;

15 c. Whether such agreements and the co-conspirators' conduct pursuant
16 to them had the effect of inflating the price of **Stryker** products used in hip and/or knee
17 implant surgery, and, if so, by how much;

18 d. Whether such agreements and the co-conspirators' conduct pursuant
19 to them violated California's Cartwright Act (Cal. Bus. & Prof. Code §§ 16700 *et seq.*);

20 e. Whether such agreements and the co-conspirators' conduct pursuant
21 to them violated section 650 of the California Business and Professions Code ("anti-
22 kickback statute");

23 f. Whether such agreements and the co-conspirators' conduct pursuant
24 to them violated section 654.2 of the California Business and Professions Code;

25 g. Whether such agreements and the co-conspirators' conduct pursuant
26 to them violated section 14107 of the California Welfare and Institutions Code;

27 h. Whether such agreements and the co-conspirators' conduct pursuant
28 to them violated section 139.3 of the California Labor Code;

1 i. Whether such agreements and the co-conspirators' conduct pursuant
2 to them violated section 12651 the California False Claims Act (Cal. Gov't Code
3 § 12651);

4 j. Whether such agreements and the co-conspirators' conduct pursuant
5 to them violated the Sherman Antitrust Act (15 U.S.C. § 1);

6 k. Whether such agreements and the co-conspirators' conduct pursuant
7 to them violated the federal Anti-Kickback Act (41 U.S.C. §§ 51 *et seq.*);

8 l. Whether such agreements and the co-conspirators' conduct pursuant
9 to them violated the Medicare fraud statute (42 U.S.C. § 1320a-7b);

10 m. Whether such agreements and the co-conspirators' conduct pursuant
11 to them violated 42 U.S.C. § 1395nn;

12 n. Whether such agreements and the co-conspirators' conduct pursuant
13 to them violated the federal False Claims Act (31 U.S.C. §§ 3720 *et seq.*);

14 o. Whether Plaintiff and members of the Class incurred increased
15 health care costs as a result of the conduct of Defendants, and each of them; and

16 p. The appropriate measure of the overall damages sustained by
17 Plaintiff and the Class.

18 34. Plaintiff is a member of the Class, and Plaintiff's claims are typical of the
19 claims of the Class members, in that Plaintiff had hip implant surgery during the Class
20 period in which the surgeon inserted one or more **Stryker** products.

21 35. Plaintiff will fairly and adequately protect the interests of the Class.
22 Plaintiff's interests are coincident with and not antagonistic to those of other members of
23 the Class. Plaintiff is represented by counsel competent and experienced in the
24 prosecution of antitrust and class action litigation.

25 36. The questions of fact and/or law common to the members of the Class
26 predominate over any questions affecting only individual members of the Class.

27 37. A class action is superior to other methods for the fair and efficient
28 adjudication of this controversy. Treatment as a class will permit a large number of

1 similarly situated individuals to adjudicate their common claims in a single forum
 2 simultaneously, efficiently, and without the duplication of effort and expense, and risk of
 3 inconsistent rulings or outcomes, that numerous individual actions would engender.

4 38. Class treatment will also permit the adjudication of relatively small claims
 5 by many Class members who otherwise could not afford to litigate an antitrust claim such
 6 as is asserted in this Complaint.

7 39. This litigation presents no difficulties in management that would preclude
 8 maintenance as a class action.

9 **VII. TOLLING OF STATUTES OF LIMITATIONS BY FRAUDULENT**
 10 **CONCEALMENT**

11 40. Throughout the relevant period, Defendants affirmatively, purposefully, and
 12 fraudulently concealed their unlawful conduct from Plaintiff and the Class.

13 41. Plaintiff and the members of the Class did not discovery, and could not
 14 discovery through the exercise of reasonable diligence, that Defendants were violating the
 15 antitrust and anti-kickback laws as alleged herein until shortly before this litigation was
 16 commenced. Plaintiff and members of the Class could not have discovered the violations
 17 earlier than that time because Defendants conducted their anticompetitive kickback
 18 conspiracy in secret, concealed the nature of their unlawful conduct and the acts in
 19 furtherance thereof, and fraudulently concealed their activities through various means and
 20 methods designed to avoid detection. The conspiracy was by its nature self-concealing.

21 42. Defendants engaged in a successful anticompetitive conspiracy, as herein
 22 alleged, which they affirmatively concealed, in at least the following respects:

23 (1) By agreeing among themselves and with the unnamed co-
 24 conspirators not to discuss publicly, and not to otherwise reveal, the nature and substance
 25 of the acts and communications in furtherance of their illegal scheme;

26 (2) By engaging in secret meetings, telephone calls, and/or other
 27 communications in order to further their illicit scheme; and/or

28 (3) By giving false and pretextual reasons for their actions and the

1 consideration exchanged between Defendants and the unnamed co-conspirators during
 2 the relevant period, providing false descriptions of the basis and reasons for any payments
 3 exchanged, other consideration provided, and/or decisions to use or recommend
 4 Defendants' devices in hip and/or knee implant surgeries.

5 43. As a result of Defendants' fraudulent concealment of their conspiracy,
 6 Plaintiff and the Class assert the tolling of any applicable statute of limitations affecting
 7 the rights of action of Plaintiff and the members of the Class.

8 **VIII. CAUSES OF ACTION**

9 **FIRST CAUSE OF ACTION**

10 **(Violation of Cartwright Act, 11 Cal. Bus. & Prof. Code §§ 16700 *et seq.*)**

12 44. Plaintiff realleges each of the foregoing paragraphs of this Complaint,
 13 incorporating them by reference as through set forth in full herein.

14 45. **Stryker** and its unnamed co-conspirators have violated California's
 15 Cartwright Act, section 16700 *et seq.* of the California Business and Professions Code, by
 16 forming one or more combinations to accomplish purposes prohibited by and contrary to
 17 the Cartwright Act. They engaged in one or more agreements, contracts, combinations,
 18 trusts, and/or conspiracies to create and maintain market dominance, resulting in
 19 artificially high prices for **Stryker** hip and knee surgery products, including without
 20 limitation implant devices and related products, such as bone cement.

21 46. **Stryker** and its unnamed co-conspirators committed acts that constituted
 22 prohibited conduct under the Cartwright Act, including without limitation making illegal
 23 agreements to reduce competition and to inflate the price and cost of **Stryker** hip and
 24 knee surgery products, unlawfully overcharging public health insurance programs in
 25 violation of the California False Claims Act as well as other statutes. **Stryker's** conduct
 26 has unfairly and unlawfully increased the price and cost of devices and other products
 27 used in hip and knee surgeries.

47. As a direct result of the unlawful and unfair actions of **Stryker** and its unnamed co-conspirators, which actions date back at least through 2002 and are continuing, Plaintiff and other members of the Class suffered financial injury by incurring out-of-pocket costs, including without limitation co-pays and health insurance premiums, for hip and/or knee surgery that were higher than they would have been absent **Stryker's** participation in the illegal and anti-competitive conspiracy. These injuries have caused and will continue to cause damages to Plaintiff and the Class.

48. As a direct and legal result of the acts of **Stryker** and its unnamed co-conspirators, Plaintiff and the Class were required to file this action, resulting in ongoing attorneys' fees, costs, and other expenses for which they seek recovery according to proof.

49. Pursuant to the Cartwright Act, Plaintiff and the Class are authorized to recover three times the damages that they sustained, plus interest and reasonable attorneys' fees, costs, and expenses.

WHEREFORE Plaintiff prays for judgment against Defendants, and each of them, as set forth below.

SECOND CAUSE OF ACTION

(Violation of California Unfair Competition Law, Cal. Bus. & Prof. §§ 17200 *et seq.*)

50. Plaintiff realleges each of the foregoing paragraphs of this Complaint, incorporating them by reference as through set forth in full herein.

51. By their wrongful conduct, as set forth in all the preceding allegations of this Complaint, Defendants, and each of them, engaged in unlawful business practices in violation of section 17200 *et seq.* of the California Business and Professions Code, California's Unfair Competition Law.

52. By their wrongful conduct, as set forth in all the preceding allegations of this Complaint, Defendants, and each of them, engaged in unfair business practices in violation of section 17200 *et seq.* of the California Business and Professions Code.

53. By their wrongful conduct, as set forth in all the preceding allegations of this Complaint, Defendants, and each of them, engaged in fraudulent business practices in violation of section 17200 *et seq.* of the California Business and Professions Code.

54. Defendants' practices are unlawful, unfair, and/or fraudulent business practices, within the meaning of section 17200 of the California Business and Professions Code, for the reasons set forth below, without limitation:

- (1) Defendants' acts and practices, as herein alleged, have violated, without limitation, California's Cartwright Act (Cal. Bus. & Prof. Code §§ 16700 *et seq.*); section 650 of the California Business and Professions Code ("anti-kickback statute"); section 654.2 of the California Business and Professions Code; section 14107 of the California Welfare and Institutions Code; section 139.3 of the California Labor Code; section 12651 of the California Government Code (California False Claims Act); the federal Sherman Antitrust Act (15 U.S.C. § 1); the Anti-Kickback Act (41 U.S.C. §§ 51 *et seq.*); the Medicare fraud statute (42 U.S.C. § 1320a-7b); 42 U.S.C. § 1395nn; and the False Claims Act (31 U.S.C. §§ 3720 *et seq.*); and/or
- (2) Defendants' acts and practices, as herein alleged, are unfair to private-pay patients, along with patients covered by publicly funded health care programs, in that they offend public policy as expressed in statutes and regulations, are unconscionable, are unscrupulous, and are oppressive; and/or
- (3) Defendants' acts and practices, as herein alleged, are fraudulent in that Defendants' affirmative misrepresentation of the basis for their payments and other consideration provided to the unnamed co-conspirators, and concealment of the facts of the magnitude and nature of their payments and other consideration provided to the unnamed co-conspirators, were likely to deceive Plaintiff and members of the Class, as well as government officials and others, into not realizing that they have incurred inflated health care

costs.

55. As a consequence of the violation by Defendants, and each of them, of California's Unfair Competition Law, Plaintiff and other members of the Class have incurred costs that they would not have incurred in the absence of Defendants' unlawful, unfair, and/or deceptive business practices, as alleged above.

56. Pursuant to section 17203 of the California Business and Professions Code, Plaintiff and the Class seek an order of this Court enjoining Defendants, and each of them, from continuing their unfair, unlawful, and/or deceptive business acts and practices. Plaintiff and the Class also seek restitution of the higher health care costs that they have been compelled to incur, accordingly to proof, by virtue of Defendants' unfair, unlawful, and/or deceptive business acts and practices.

WHEREFORE Plaintiff prays for judgment against Defendants, and each of them, as set forth below.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all members of the Class, requests judgment and relief as follows:

1. That the Court, pursuant to Rule 23 of the Federal Rules of Civil Procedure, certify the case as a class action on behalf of the proposed Class, designate Plaintiff as the representative of the Class, and designate Plaintiff's counsel of record as Class Counsel;

2. That the Court adjudge and decree that the acts of the Defendants are unlawful and in violation of California's Cartwright Act and the California Unfair Competition Law;

3. That the Court enter judgment against Defendants, jointly and severally, and in favor of Plaintiff and the Class for restitution and/or for damages as allowed by law as determined to have been sustained by them;

4. That the Court permanently enjoin and restrain each of the Defendants and their successors, assigns, parents, subsidiaries, affiliates, and transferees, and their respective officers, directors, agents, and employees, and all other persons acting or

1 claiming to act on behalf of Defendants or in concert with them, in any manner, directly
2 or indirectly, from continuing, maintaining, or renewing the combinations, conspiracy,
3 agreement, understanding, or concert of action as alleged herein;

4 5. That the Court award Plaintiff and the Class attorneys' fees and costs, along
5 with pre-judgment and post-judgment interest as permitted by law; and

6 6. That the Court award Plaintiff and the Class such other and further relief as
7 may be necessary and appropriate.

8
9 Dated: March 24, 2008

COTCHETT, PITRE & McCARTHY

COREY, LUZAICH, PLISKA,
de GHETALDI & NASTARI, LLP

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13 By: 

FRANK M. PITRE

14 Attorneys for Plaintiff and the Class

15
16 **DEMAND FOR JURY TRIAL**

17 On behalf of herself and the Class, Plaintiff hereby request trial by jury as to all
18 issues so triable.

19
20 Dated: March 24, 2008

COTCHETT, PITRE & McCARTHY

COREY, LUZAICH, PLISKA,
de GHETALDI & NASTARI, LLP

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24 By: 

FRANK M. PITRE

25 Attorneys for Plaintiff and the Class
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EXHIBIT A

Non Prosecution Agreement

1. Stryker Orthopedics, a division of Howmedica Osteonics Corp. (the "Company"), by its undersigned attorneys, and the United States Attorney's Office for the District of New Jersey (the "Office"), enter into this Non Prosecution Agreement (the "NPA"). Except as specifically provided below, the NPA shall be in effect for a period of eighteen (18) months from the date it is fully executed (the "Effective Date").

2. The Company agrees to post the NPA prominently on the Company website for the duration of the NPA.

General Commitment to Compliance and Remedial Actions

3. The Company commits itself to exemplary corporate citizenship, best practices of effective corporate governance, the highest principles of honesty and professionalism, the integrity of the operation of federal health care programs including Medicare and Medicaid, the sanctity of the doctor-patient relationship, and a culture of openness, accountability, and compliance throughout the Company. The Company also commits not to attempt to influence medical practitioners and institutions to use the Company's products through the use of unlawful inducements. To advance and underscore this commitment, the Company agrees to take, or has acknowledged that it has taken, the remedial and compliance measures set forth herein.

4. In matters relating to federal health care laws, the Company will cooperate fully with all federal law enforcement and regulatory agencies, including but not limited to: the Criminal and Civil Divisions of the Office; the United States Department of Justice, Criminal and Civil Divisions; the United States Department of Health and Human Services, Office of Inspector General ("HHS-OIG"); the Federal Bureau of Investigation ("FBI"); and the United States Postal Inspection Service ("USPIS"); provided, however, that such cooperation shall not require the Company's waiver of attorney-client and work product protections or any other applicable legal privileges. Nothing in this NPA shall be construed as a waiver of any applicable attorney-client or work product privileges (hereafter "privilege").

5. The Company shall communicate to its employees and distributors that Company personnel and agents are required to report to the Company any suspected violations of any federal or state laws, regulations, federal health care program requirements, or internal policies and procedures.

6. The Company shall implement or continue its operation of an effective corporate compliance program and function to ensure that internal controls are in place to prevent recurrence of the activities that resulted in this NPA. The Company shall also develop and implement policies, procedures, and practices designed to ensure compliance with federal health care program requirements, including the Anti-Kickback Statute, with respect to all its dealings with Consultants, as defined herein, and others who cause the purchase of Company orthopedic products in the United States.

7. The Company shall adhere to the AdvaMed Code of Ethics on Interactions with Health Care Professionals. The AdvaMed Code can be found at www.advamed.org. The principles set forth in the AdvaMed Code are expressly incorporated as compliance requirements under this NPA.

8. The Company agrees that its President and CEO, General Counsel, Compliance Officer, and appropriate Company executives will meet quarterly with the Office and the Monitor, in conjunction with the Monitor's quarterly reports described in paragraph 16 herein.

Definitions

9. "Consultant" is defined as any United States-based orthopedic surgeon, PhD, health care professional, non-physician practitioner, medical fellow, resident or student, or any employee or agent of any educational or health care organization the Company retains for any personal or professional services or compensates or remunerates in any way, directly or indirectly, for or in anticipation of personal or professional services relating to hip and knee reconstruction and replacement. The term Consultant shall not include accountants, auditors, attorneys, fair market value specialists, CME providers, reimbursement specialists, any non-physician engineering or marketing consultants, or any other types of non-physician professionals or entities excluded from this definition by the Monitor upon recommendation by the Company.

10. "Consulting Agreement" includes all contracts with Consultants for services to be performed on behalf of the Company. This includes, but is not limited to, agreements for compensation, payments, remuneration, honoraria, fellowships, professional meetings, speaking engagements, teaching, publications, clinical studies, fee-for-service consulting, product development and license agreements, research, and professional services agreements. The term "Consulting Agreement" also includes agreements to provide grants, donations, sponsorships and other forms of payment to medical educational organizations, medical societies and training institutions.

11. "Consulting Services" or "Services" include any and all professional services provided by a Consultant to or on behalf of the Company.

12. "Payment" shall include any and all compensation or remuneration paid to or for the benefit of Consultants, including but not limited to payments and reimbursements for personal or professional services, any type of securities, registered or unregistered, meals, entertainment, travel, gifts, grants, honoraria, charitable contributions, donations, sponsorships, research grants, clinical studies, professional meetings, product training, medical education, research funding, product development services, in-kind services (e.g., use of aircraft), advertising, promotion, and marketing expenses or support, and royalties or other payments for transfer of documented intellectual property. Unless otherwise approved by the Monitor, the Company shall only compensate or remunerate Consultants through direct Payments made pursuant to a Consulting Agreement. The Company shall not knowingly make any Payments to

Consultants indirectly, such as through distributors.

Retention and Obligations of a Monitor

13. The Company agrees that until the expiration of this NPA, it will retain an outside, independent individual (the "Monitor") selected by the Office, after consultation with the Company, to evaluate and monitor the Company's compliance with the NPA. Among the conditions of the Monitor's retention are that the Monitor is independent of the Company, the Monitor works exclusively for and at the direction of the Office, and no attorney-client relationship shall be formed between the Monitor and the Company.

14. The Monitor shall have access to all non-privileged Company documents and information the Monitor determines are reasonably necessary to assist in the execution of his or her duties. The Monitor shall have the authority to meet with any officer, employee, or agent of the Company. The Company shall use its best efforts to have its independent distributors for hip and knee reconstruction and replacement products and their employees and agents fully cooperate and meet with the Monitor as requested. For all distributor agreements for hip and knee reconstruction and replacement products and renewals executed after the Effective Date, the Company shall require provisions allowing the Monitor access to non-privileged relevant documents and information relating to Consulting Agreements and Services, and compliance with all applicable provisions of the NPA.

15. The Monitor shall conduct a review and evaluation of all of the Company's policies, practices, and procedures relating to compliance with the NPA and the following subjects, and report and make written recommendations as necessary ("Recommendations") to the Company and the Office concerning same:

- a. The corporate structure and governance of the Company relative to selecting, engaging, and paying Consultants;
- b. The effectiveness of the procedures and practices at the Company to select, engage, and pay Consultants in exchange for the provision of Services to the Company, as well as the related legal, compliance, research and development, marketing, sales, internal controls, and finance functions;
- c. The effectiveness of the training and education programs in the following areas: federal health care laws concerning relationships between the Company and Consultants; Medicare, Medicaid and other health care benefit programs; ethics; and compliance and corporate governance issues relating to federal health care laws;
- d. The structure and content of agreements memorializing arrangements to engage and pay Consultants in exchange for the provision of Services to

the Company, and the Company's payments to Consultants made thereunder. The Monitor shall have access to and may review all previously entered agreements to the extent he or she reasonably deems necessary; and

- e. The influence, actual or potential, over Consultants' selection of Company products as a result of the financial relationships between the Company and those Consultants.

16. The Monitor shall, *inter alia*:

- a. Monitor and review the Company's compliance with this NPA and all applicable federal health care laws, statutes, regulations, and programs, including the Anti-Kickback Statute, relating to the sale and marketing of hip and knee reconstruction and replacement products;
- b. As requested by the Office, cooperate with the Criminal and Civil Divisions of the Office, the United States Department of Justice, Criminal and Civil Divisions, HHS-OIG, the FBI and the USPIS, and, as requested by the Office, provide information about the Company's compliance with the terms of this NPA;
- c. Provide written reports to the Office, on at least a quarterly basis, concerning the Company's compliance with this NPA. In these reports or at other times the Monitor deems appropriate, the Monitor shall make Recommendations to the Company to take any steps he or she reasonably believes are necessary for the Company to comply with the terms of this NPA and enhance future compliance with federal health care laws as related to the sale and marketing of hip and knee reconstruction and replacement products; and, as agreed by the Company or mandated by the Office pursuant to paragraph 43, require the Company to take such steps when it is agreed that such steps are reasonable and necessary for compliance with the NPA. The first report to the Office shall be due three months after the Effective Date, and subsequent reports shall be made quarterly thereafter;
- d. After consultation with the Company and the Office, and allowing reasonable time for the Company or the Office to object, the Monitor may retain, at the Company's expense, consultants, accountants or other professionals the Monitor reasonably deems necessary to assist the Monitor in the execution of the Monitor's duties. Before retention, these consultants, accountants or other professionals shall provide to the Monitor and the Company a proposed budget. If the Company believes the costs to be unreasonable, the Company may bring the matter to the Office's attention for dispute resolution by the Office;

- e. Monitor the preparation of and approve the Needs Assessment and any Modifications thereto described in paragraphs 24-26 herein;
- f. Review and approve all new or renewed Consulting Agreements executed between the Effective Date and the date the Needs Assessment is approved;
- g. Review in his or her discretion any requests for Consulting Services made between the Effective Date and the date the Needs Assessment is approved;
- h. Review in his or her discretion any Payments made to Consultants between the Effective Date and the date the Needs Assessment is approved;
- I. Review and approve in his or her discretion all Consulting Agreements with new Consultants executed after the Needs Assessment is approved;
- j. Review in his or her discretion any Consulting Agreement renewals executed after the Needs Assessment is approved;
- k. Review in his or her discretion any requests for Consulting Services made after the Needs Assessment is approved;
- l. Review in his or her discretion any Payments made to Consultants after the Needs Assessment is approved;
- m. Review in his or her discretion any payments made to CME providers, reimbursement specialists, any non-physician engineering or marketing consultants, or other excluded consultants as described in paragraph 9;
- n. Review in his or her discretion any payments made to Consultants as honoraria, fellowships, gifts, donations, charitable contributions and other non-Service payments as described in paragraph 24;
- o. Review and approve any new or substitute Consultants as described in paragraphs 30 and 31 herein;
- p. Approve any changes to the Hourly Rate or any Payments made at a rate other than the Hourly Rate, as described in paragraphs 33-35 herein;
- q. Monitor the Consultant disclosure obligations as described in paragraphs 37-38 herein; and

- r. Monitor the information received by the confidential hotline and e-mail address as described in paragraph 40 herein.

In the event the Monitor opposes any Consulting Agreement, request for Consulting Services, or request for Payment, the Monitor will promptly meet with the Company to discuss his or her concerns. The Consulting Agreement shall not be executed, the Consulting Services shall not be rendered, or the Payment shall not be made unless and until the Monitor's objections are remedied. All actions of the Monitor in this regard shall be subject to review by the Office and shall not require the Company to breach any existing contractual requirements so long as they comply with all applicable laws. The Office will act promptly to resolve any issues on a good faith and reasonable basis.

17. The Company shall promptly notify the Monitor and the Office in writing of any credible evidence of criminal corporate conduct as well as of any known criminal investigations of any type of the corporation or any of its officers or directors that becomes known to the Company after the Effective Date. In addition, the Company shall promptly notify the Monitor and the Office in writing of any credible evidence of criminal conduct or serious wrongdoing relating to federal health care laws by the Company, its officers, employees and agents. The Company shall provide the Monitor and the Office with all relevant non-privileged documents and information concerning such allegations, including but not limited to internal audit reports, letters threatening litigation, "whistleblower" complaints, civil complaints, and documents produced in civil litigation. In addition, the Company shall report to the Monitor and the Office concerning its planned investigative measures and any resulting remedial measures, internal and external. The Monitor in his or her discretion may conduct an investigation into any such matters; and nothing in this paragraph shall be construed as limiting the ability of the Monitor to investigate and report to the Company and the Office concerning such matters.

Remedial Measures

Responsibilities of Compliance Office

18. The Compliance Office ("Compliance Office") and Compliance Officer ("Compliance Officer") shall be responsible for monitoring the day-to-day compliance activities of the Company. The Compliance Officer shall report directly to the CEO and President and shall not be a subordinate to the chief legal officer, the chief financial officer, or any sales or marketing officers. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters to the Company Board of Directors and is authorized to report on such matters directly to the Company Board of Directors at any time.

19. The Compliance Officer shall have the authority to meet with, and require reports and certifications on any subject from, any officer or employee of the Company.

20. The Compliance Office shall be responsible for oversight, evaluation, and approval of the Company's Needs Assessments (described more fully at paragraphs 24-26), and

shall evaluate and approve requests for Consulting Agreements, Services, and Payments, subject to review and approval by the Monitor as set forth in paragraph 16.

21. The Compliance Office shall be responsible for approving the Consulting Services budget. All requests for Consulting Services and Payments must be made to and approved by the Compliance Office. Any Payments to or for the benefit of a Consultant must be approved by the Compliance Office, subject to review of the Monitor as set forth in paragraph 16.

22. Consulting Agreements shall be managed by Company employees who have no sales responsibilities and who report to the Compliance Office on Consulting issues. These employees shall interface directly with the Consultants on the terms of their Consulting Agreements and on issues relating to Payments.

23. From the Effective Date until the Needs Assessment is approved, all requests for Consulting Services and Payments shall be pre-approved by the Compliance Office. In considering these requests, the Compliance Office and any other Company personnel with knowledge of the request shall evaluate the bona fides of the activity for which the Services or Payments are requested, subject to review of the Monitor. No Consulting Services may be approved unless the Compliance Office verifies that the Company has a bona fide commercial need for such services. No Payments may be made without appropriate documentation and verification of services rendered on a standard form to be developed by the Compliance Office and approved by the Monitor.

Needs Assessment

24. The Company shall complete a Needs Assessment no later than December 31, 2007, and annually thereafter. The Needs Assessment may be modified if bona fide, commercially reasonable, unexpected business needs arise ("Modification"). The Needs Assessment must reflect the Company's expected, commercially reasonable needs for all Consulting Services to fulfill its medical, clinical, training, educational, and research and development needs. The Needs Assessment shall also contain a budget for the total amount of honoraria, fellowships, gifts, donations, charitable contributions, and any other payments contemplated to be made to Consultants for which no Consulting Services are provided. The Needs Assessment and any Modifications as defined herein shall be prepared in consultation with those areas of the Company that have bona fide needs for the services to be performed. The Needs Assessment and any Modifications must be approved by the Compliance Officer and the Monitor before they are finalized. As of January 1, 2008, the Needs Assessment and any Modifications shall be used as a basis for Consultant selection and all Consulting Agreements, Services and Payments. The Compliance Officer shall attest to the best of his or her knowledge, after conducting reasonable due diligence, that the Needs Assessment and any Modifications reflect the bona fide, commercially reasonable consulting needs of the Company.

25. The Needs Assessment shall establish or incorporate by reference detailed

protocols or procedures that must be followed before a Consulting Agreement will be authorized. The Needs Assessment must identify and quantify the services needed within each discrete service category (e.g., operating room training, speaking engagements, clinical studies, product development groups), and provide written support for the needs. The Needs Assessment must set forth the nature of the services needed, the range of hours or other quantitative measure needed to complete the services, the number of Consultants needed, and the maximum fair market value compensation to be paid for each consulting service. The Needs Assessment shall also identify the qualifications and expertise required to perform the services. The Needs Assessment shall ensure that Services are distributed appropriately to all regions of the country.

26. The Needs Assessment and any approved Modifications shall be used to define and limit all Consulting Services performed for the Company for the ensuing year. All Consulting Agreements entered into by the Company shall be for services specified and enumerated by the Needs Assessment and any approved Modifications. No Consulting Agreement shall be entered into with any Consultant for services outside those specified in the Needs Assessment and any approved Modifications, or for services exceeding the number of services specified in the Needs Assessment and any approved Modifications. For example, if the Needs Assessment specifies that the Company will require Consultants to conduct 50 speaking engagements on a particular topic, once the total number of contracted-for speaking engagements reaches 50, the Company may not engage any additional Consultants for such speaking engagements unless it obtains an approved Modification.

27. The Company shall maintain a record of all Consulting Services provided under the Needs Assessment and any Modification. Monthly reports will be issued by the Compliance Office to the Monitor and to senior executives in the areas in which services are provided summarizing the Consulting Services provided or submitted for Payment, by Consultant, by region, and by total, with a list of services left to be provided during the calendar year in fulfillment of the Needs Assessment.

Consulting Agreements

28. All Consulting Agreements shall be in writing and executed by the Compliance Officer, the President, the Chief Legal Officer, the Director of R&D for product development and research agreements, and the Director of Clinical for clinical services agreements (including clinical trials, clinical studies, follow-up visits). On an annual basis, the Compliance Officer, the Director of R&D for product development and research agreements, and the Director of Clinical for clinical services agreements shall attest and certify in writing that, based on their reasonable inquiry and knowledge, all Consulting Agreements and all Consulting Services performed thereunder were bona fide, commercially reasonable, and compliant with all federal health care programs. The Company shall not enter into Consulting Agreements with Consultants through any third parties, including distributors.

29. All Consulting Agreements for Consulting Services to be rendered in 2008 and thereafter shall be for a term of the calendar year, with the exception of product development

agreements that could result in the payment of royalties, clinical agreements, and external research agreements, which may be for a length appropriate to the type of Service being rendered, upon approval of the Monitor. All Consulting Agreements shall identify the specific Services to be provided as defined by the Needs Assessment and any Modification thereto, and specify the rate to be paid for each Service. The Company may not enter into Consulting Agreements for Services exceeding the total number of Services set forth in the Needs Assessment and any Modification thereto. Consultants shall be paid only for the actual time expended in providing Consulting Services, in hourly billing increments or other reasonable quantitative measure as identified in the Needs Assessment, without regard to the total amount of consulting services permissible under their Consulting Agreements.

New and Substitute Consultants

30. The Compliance Office, in consultation with the Monitor and appropriate Company employees, shall conduct an evaluation of each new Consultant to be considered for a Consulting Agreement. This evaluation shall ensure the proposed Consultant's qualifications and experience are commensurate with those required by the Needs Assessment and any Modification thereto, and that any new relationship meets an unfilled bona fide commercial need of the Company.

31. In the event a Consultant is unable to provide service to the Company under a Consulting Agreement in any given year, the Company may substitute another Consultant or retain a new Consultant to perform the specified yet unfulfilled Consulting Services of the Consulting Agreement. The substitute Consultant must be authorized by the Compliance Officer and approved by the Monitor after conducting a substantive review of the Consultant's qualifications and expertise.

Payments to Consultants

32. A Company employee or representative must be present for every Consulting Service, except that the Monitor, upon application by the Compliance Office, may exempt certain Services from this requirement (such as collection of clinical study data, travel or preparation time). Upon completion of the Consulting Service, both the Company employee (or representative) in attendance and the Consultant must independently verify in writing that the Service took place, identify the participants present and length of service, and summarize the Service provided. These verifications must be certified, made under penalty of perjury, and submitted to the Compliance Office within ninety (90) calendar days of the date of the Service and as a condition precedent to any Payments being issued under a Consulting Agreement.

33. For all Consulting Agreements entered into after the Effective Date of this NPA, the Company agrees to make Payments to Consultants at a fair market value hourly rate ("Hourly Rate") of no more than \$500 per hour for time actually expended by a Consultant performing Consulting Services. In the event the Company wishes to make Payments to a Consultant at a higher Hourly Rate or at a different rate because of the Consultant's special expertise or the

nature of the service (such as a per patient rate for clinical studies), the Company must obtain or have obtained a fair market value analysis conducted by an independent organization with expertise in valuation as approved or accepted by the Monitor. Any changes to the Hourly Rate or Payments other than at the Hourly Rate must be approved by the Monitor.

34. With respect to product development agreements and renewals entered into after the Effective Date and for all Services to be rendered after January 1, 2008, the Company shall pay a Consultant on a product development team for the actual time spent providing Services to the Company, at no more than the Hourly Rate. In addition to the Hourly Rate payments, the Company may pay each member of a product development team royalties on any product the team may develop. The number of Consultants serving on a product development team must not exceed the number reasonably necessary to achieve the identified design and development needs of the project. The aggregate royalties paid per project to all Consultants shall not exceed fair market value expressed as a certain percentage of all domestic and international product sales of the product or products that are the subject of the product development agreement as proposed by the Company and approved by the Monitor. These royalty payments and Hourly Rate payments shall be the only compensation a Consultant may receive for participation on a product design team; that is, the Company shall not make any flat rate payments or minimum guaranteed payments in lieu of or in addition to Hourly Rate payments and royalty payments. The Company may offset royalty payments to a Consultant with Hourly Rate payments for Services the Consultant appropriately performed. The Company may pay royalties to a Consultant only for Intellectual Property received by the Company for products that have actually been sold. (Products may be considered to have been sold when the products are transferred to an unrelated third-party or to a Company affiliate located outside the United States.) If the Intellectual Property has been patented in the United States, royalty payments may not extend beyond the life of the U.S. patent. If the Intellectual Property has not been patented, royalties may not extend beyond a reasonable period (in light of factors such as the life cycle and commercial advantages of the products and Intellectual Property and the burden of administering the royalty arrangement). As used herein, "Intellectual Property" includes patents, trade secrets and know-how received by the Company from the Consultant or product development team under a product development agreement. The Company shall establish processes for reviewing individual Consultant contributions to determine whether Intellectual Property has been provided to the Company, such processes shall be approved by the Monitor. The persons responsible for deciding whether Intellectual Property has been provided shall not be involved in sales functions, and their decision is subject to Monitor approval. The identity of royalty-bearing products must be reasonable (in light of factors such as the scope of Intellectual Property transferred, the relationship of the Intellectual Property to the products and the burden of administering the royalty arrangement) and is subject to Monitor approval. Royalties must not be paid in advance or in anticipation of product development that might result in a royalty. No royalty may be paid to a Consultant that is earned by virtue of the use of the product in question by the Consultant or by any member of a practice group of which the Consultant is a member. In lieu of royalties, a fixed amount may be paid for Intellectual Property provided to the Company, provided the amount is commercially reasonable and subject to Monitor approval. For patents and patent applications that are not assigned or licensed to the Company under a product

development agreement, royalties, patent fees, patent costs, and/or a fixed amount may be paid for the acquisition or licensing of such patents and patent applications, subject to Monitor approval.

35. All Consultants on product design teams shall submit invoices, at least quarterly, and supporting documentation for services rendered to the Company's design team project manager for approval, prior to any Payments being made. A Company employee shall be present at all meetings of product development teams. That employee shall report the date, the participants, and a summary of the meeting to the project manager. The project manager must certify in writing that the invoices reflect bona fide services provided by the Consultant. These invoices, supporting documentation, and certification must be submitted to the Compliance Office for Payment.

36. In addition, the following practices have been or shall be implemented no later than sixty (60) calendar days after the Effective Date:

- a. The Company may not make Payments to Consultants for collection of clinical data unless there is a written agreement defining the required procedures and protocol and the amount of clinical data to be collected by the Consultant, pre-approved by the Director of Clinical.
- b. The Company may not make Payments to Consultants for research unless there is a written agreement defining the required procedures and protocol, pre-approved by the Director of Research and Development. The Company may not provide unrestricted grants to Consultants.
- c. The Company may not fund any fellowships for fellows who work with any Consultant, with the exception of fellowship funding to legitimate medical education foundations or institutions so long as that funding is approved in advance by the Compliance Office and the Monitor;
- d. The Company may not make charitable contributions to 501(c)(3) organizations that are, to the best of the Company's knowledge after reasonable due diligence is conducted, controlled by a Consultant or an immediate family member of a Consultant, or at which an immediate family member of a Consultant is employed. All charitable contributions must be approved in advance by the Compliance Office in consultation with the Monitor. The Monitor has the discretion to make exceptions to the above standard;
- e. Other than Consulting Agreements, the sale of products and associated equipment and instruments and the purchase of Intellectual Property, the Company may have no commercial dealings with any Consultant or any entity or organization that the Company has reason to believe, after

reasonable due diligence is conducted, is controlled by the Consultant or an immediate family member of the Consultant. The Monitor has the discretion to make exceptions to the above standard;

- f. The Company shall not hire or engage as an agent or distributor anyone in order to induce a Consultant to use or purchase Company products; and
- g. The Compliance Office shall notify the Monitor of any employees or independent distributors who are known to bear an immediate family relationship to any Consultant. In such cases, the Monitor may recommend changes in assignment or case coverage to avoid actual or perceived conflict of interest.

Disclosure

37. All new Consulting Agreements and renewals shall require Consultants to disclose their financial engagement with the Company to their patients, as well as affiliated hospitals.

38. Within thirty (30) calendar days of the Effective Date of this NPA, the Company shall prominently feature on its web site the name, city, and state of residence for each of the Company's Consultants who were retained at any time in 2007, who provided Consulting Services to the Company at any time in 2007, or who received any Payments from the Company in 2007. The Company shall also there disclose the Payments made to each Consultant to date in 2007 within \$25,000 increments, and, within sixty (60) calendar days of the Effective Date, all other Payments made in other than dollar form. Within ten (10) calendar days after a new Consulting Agreement or renewal is executed, the Company shall post the name of the Consultant on its web site. If the Company has or does enter into a Consulting Agreement with an entity rather than an individual, the Company shall post both the name of the entity and the individual providing Services to the Company under the Consulting Agreement. Payment information shall be updated quarterly during the term of this NPA to reflect the total Payments made to each Consultant within \$25,000 increments, and all other Payments made in other than dollar form. The Company must also disclose this information to the Consultant's affiliated hospitals.

Compliance, Training and Hotline

39. The Company agrees to enhance, support, and maintain its existing training and education programs, including any programs recommended by the Monitor pursuant to paragraph 15, above. The programs, which shall be reviewed and approved by the Company CEO and President and the Monitor, shall be designed to advance and underscore the Company's commitment to exemplary corporate citizenship, to best practices of effective corporate governance and the highest principles of integrity and professionalism, and to fostering a culture of openness, accountability and compliance with federal health care laws throughout

the Company. Completion of such training shall be mandatory for all Company officers, executives, and employees who are involved in Sales, Marketing, Legal, Compliance, and other senior executives at the Company as proposed by the Company and approved by the Monitor (collectively the "Mandatory Participants"). Such training and education shall cover, at a minimum, all relevant federal health care laws and regulations, internal controls in place concerning Consultants and their Consulting Agreements with the Company, and the obligations assumed by, and responses expected of, the Mandatory Participants upon learning of improper, illegal, or potentially illegal acts relating to the Company's sales and marketing of hip and knee reconstruction and replacement products. The Company CEO and President shall communicate to the Mandatory Participants, in writing or by video, their review and endorsement of the training and education programs. The Company shall commence providing this training within ninety (90) calendar days after the Effective Date of this NPA.

40. The Company agrees to establish and/or maintain a confidential hotline and e-mail address, of which Company employees, agents, and customers are informed and can use to notify the Company of any concerns about unlawful conduct, other wrongdoing, or evidence that Company practices do not conform to the requirements of this Agreement. This hotline and e-mail address shall be reviewed by the Monitor. The Company shall post information about this hotline on its website and shall inform all those who avail themselves of the hotline of the Company's commitment to non-retaliation and to maintain confidentiality and anonymity with respect to such reports.

Disclosure of Monitor Reports

41. The Company agrees that the Monitor may disclose his or her written reports, as directed by the Office, to any other federal law enforcement or regulatory agency in furtherance of an investigation of any other matters discovered by, or brought to the attention of, the Office in connection with the Office's investigation of the Company or the implementation of this NPA. The Company may identify any trade secret or proprietary information contained in any report, and request that the Monitor redact such information prior to disclosure.

Replacement of Monitor

42. The Company agrees that if the Monitor resigns or is unable to serve the balance of his or her term, a successor shall be selected by the Office, in consultation with the Company, within forty-five (45) calendar days. The Company agrees that all provisions in this NPA that apply to the Monitor shall apply to any successor Monitor. The Company shall be given the opportunity to meet the successor Monitor before he or she is retained and to submit any objections to the Office.

Adopting Recommendations of Monitor

43. The Company shall adopt all Recommendations contained in each report submitted by the Monitor to the Office, unless the Company objects to the Recommendation and the Office agrees that adoption of the Recommendation should not be required. The Monitor's reports to the Office shall not be received or reviewed by the Company prior to submission to the

Office; such reports will be preliminary until the Company is given the opportunity, within ten (10) calendar days after the submission of the report to the Office, to comment to the Monitor and the Office in writing upon such reports, and the Monitor has reviewed and provided to the Office responses to such comments, upon which such reports shall be considered final. In the event the Company disagrees with any Recommendation of the Monitor, the Company and the Monitor may present the issue to the United States Attorney for his consideration and final decision, which is non-appealable.

Meeting with the U.S. Attorney

44. Within thirty (30) calendar days of the Effective Date of this NPA, the Company agrees to call a meeting, on a date mutually agreed upon by the Company and the Office, of Company senior compliance, sales, and marketing executives, and any other Company employees who the Company desires to attend, such meeting to be attended by the United States Attorney and other representatives of the Office for the purpose of communicating the goals and expected effect of this NPA.

Cooperation

45. The Company agrees that its continuing cooperation during the term of this NPA shall include, but shall not be limited to, the following:

- a. Not engaging in or attempting to engage in any criminal conduct;
- b. Completely, truthfully and promptly disclosing all non-privileged information concerning all matters about which the Office and other government agencies designated by the Office may inquire with respect to the Company's compliance with health care laws, and continuing to provide the Office, upon request, all non-privileged documents and other materials relating to such inquiries;
- c. Consenting to any order sought by the Office permitting disclosure to the Civil Division of the United States Department of Justice of any materials relating to compliance with federal health care laws that constitute "matters occurring before the grand jury" within the meaning of Rule 6(e) of the Federal Rules of Criminal Procedure. If the Company asserts that any such any material contains trade secrets or other proprietary information, the Company shall propose redactions to the Office prior to disclosure to any other governmental entity, or the material shall be accompanied by a prominent warning notifying the agency of the protected status of the material;
- d. Making available current Company officers and employees and using its best efforts to make available former Company officers and employees to provide information and/or testimony at all reasonable times as requested

by the Office, including sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities as may relate to matters involving compliance with health care laws. The Company is not required to request of its current or former officers and employees that they forego seeking the advice of an attorney nor that they act contrary to that advice. Cooperation under this paragraph shall include, upon request, identification of witnesses who, to the Company's knowledge, may have material non-privileged information regarding the matters under investigation;

- e. Providing testimony, certifications, and other non-privileged information deemed necessary by the Office or a court to identify or establish the original location, authenticity, or other evidentiary foundation necessary to admit into evidence documents in any criminal or other proceeding relating to compliance with health care laws as requested by the Office;
- f. The Company acknowledges and understands that its future cooperation is an important factor in the decision of the Office to enter into this NPA, and the Company agrees to continue to cooperate fully with the Office, and with any other government agency designated by the Office, regarding any issue about which the Company has knowledge or information with respect to compliance with health care laws;
- g. This agreement to cooperate does not apply to any information provided by the Company to legal counsel in connection with the provision of legal advice and the legal advice itself, or to information or documents prepared in anticipation of litigation, and nothing in this NPA shall be construed to require the Company to provide any such information or advice to the Office or any other government agency; and
- h. The cooperation provisions in this paragraph shall not apply in the event that the Office pursues a criminal prosecution against the Company.

Breach of Agreement

46. Should the Office determine, in good faith and in its sole discretion, during the term of this NPA that the Company has committed any criminal conduct relating to compliance with health care laws subsequent to the Effective Date of this NPA, the Company shall, in the discretion of the Office, thereafter be subject to prosecution by this Office for any criminal conduct subsequent to October 25, 2005.

47. Should the Office determine in good faith and in its sole discretion that the Company has knowingly and willfully breached any material provision of this NPA, the Office shall provide written notice to the Company of the alleged breach and provide the Company with a two-week period from receipt of such notice in which to make a presentation to the Office to

demonstrate that no breach occurred, or, to the extent applicable, that the breach was not material or knowingly and willfully committed or has been cured. The parties understand and agree that should the Company fail to make a presentation to the Office within the two-week period after receiving written notice of an alleged breach, it shall be conclusively presumed that the Company is in breach of this NPA. In the event the Office determines, in good faith and in its sole discretion, that a second material breach has occurred, or that the first material breach has not been adequately cured, the Office shall provide written notice to the Company of the breach, and the breach may result, in the sole discretion of the Office, in the prosecution of the Company relating to the allegations that resulted in the NPA for criminal conduct subsequent to October 25, 2005. In the event of any breach of this NPA that results in a prosecution of the Company, such prosecution may be premised upon any conduct occurring after October 25, 2005. The parties further understand and agree that the determination whether the Company has breached this NPA rests solely in the discretion of the Office, and the exercise of discretion by the Office under this paragraph is not subject to review in any court or tribunal outside the Department of Justice.

48. In the event of a breach of this NPA as defined in paragraph 46 or 47 above, the Company may be subject to exclusion by OIG-HHS from participation in all federal health care programs. Such exclusion shall have national effect and shall also apply to all other federal procurement and non-procurement programs. Federal health care programs shall not pay anyone for services or items manufactured, furnished, or distributed by the Company in any capacity while the Company is excluded. This payment prohibition applies to the Company and all other individuals and entities (including, for example, anyone who employs or contracts with the Company, and any hospital or other provider where the Company provides services). The exclusion applies regardless of who submits the claim or other request for payment. The Company shall not submit or cause to be submitted to any federal health care program any claim or request for payment for services or items manufactured, furnished, or distributed by the Company during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. The Company further agrees to hold the federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for services or items manufactured, furnished or distributed to such providers, beneficiaries or sponsors after the effective date of the exclusion. The Company waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion the Company wishes to apply for reinstatement, the Company must submit a written request for reinstatement to the OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. The Company will not be reinstated unless and until the OIG approves such request for reinstatement.

Waivers and Limitations

49. The Company agrees that, if after the Effective Date, it sells all or substantially all of the Company's business operations as they exist as of the Effective Date to a single purchaser

or group of affiliated purchasers during the term of this NPA, or merges with a third party in a transaction in which the Company is not the surviving entity, the Company shall include in any contract for such sale or merger a provision binding the purchaser, successor, or surviving entity to the obligations contained in this NPA.

50. Nothing in this NPA affects in any way any civil, administrative, regulatory claims, causes of action, or rights of any federal or state agency.

51. Nothing in this NPA restricts in any way the ability of the Office to investigate and prosecute any current or former Company officer, employee, agent or attorney.

52. It is understood that this NPA is limited to the Company and the Office, and it cannot bind other federal, state or local authorities. However, the Office will bring this NPA and the cooperation of the Company and its compliance with its other obligations under this NPA to the attention of other prosecuting offices, if requested to do so.

The Full Agreement

53. This NPA constitutes the full and complete agreement between the Company and the Office and supersedes any previous agreement between them, with the exception of the letter from this Office dated October 25, 2005. No additional promises, agreements, or conditions have been entered into other than those set forth in this NPA and the letter from this Office dated October 25, 2005, and none will be entered into unless in writing and signed by the Office, Company counsel, and a duly authorized representative of the Company. It is understood that the Office may permit exceptions to or excuse particular requirements set forth in this NPA at the written request of the Company or the Monitor, but any such permission shall be in writing.

AGREED TO:

Michael Mogul
Chief Executive Officer and President
Stryker Orthopedics, a division of
Howmedica Osteonics Corporation

Christopher J. Christie
United States Attorney
District of New Jersey

Date:_____

Date:_____

Herbert J. Stern
Stern & Kilcullen
Counsel for Stryker Orthopedics